

REMARKS

I. STATUS OF THE CLAIMS

Claims 1-12 are pending.

Claims 1-12 stand rejected.

Claims 1-12 have been amended. No new matter has been added.

II. DEFECTIVE DECLARATION

The applicant is in the process of obtaining a new declaration that complies with 37 C.F.R. § 1.67(a). The new declaration will be forwarded to the Patent Office as soon as it is available.

III. OBJECTION TO DRAWINGS

The Examiner has objected to the drawing under 37 C.F.R. § 1.83(a) because the drawing does not show the following features of the invention specified in the claims: (1) means for locating several positions of the femur during motions thereof; (2) the means for imposing a constraint to the center of rotation without immobilizing it; and (3) the calculation means, all recited in claim 12.

In response, applicant hereby submits the following amendments to the specification and Figure 1:

(1) The “means for locating several positions of the femur during motions thereof” is illustrated by the feature identified with reference number 20 in Figure 1. As discussed further in Section IV, the specification has been amended accordingly in the paragraph that begins on page 7, line 3. Because the means 20 for locating several positions of the femur during motions

thereof was already illustrated in the originally-filed Figure 1, no new matter is added by this amendment.

(2) The "means for imposing a constraint to the center of rotation without immobilizing it" is described in the originally-filed specification at page 6, lines 19-21, and lines 28-30 but was not illustrated in originally-filed Figure 1. Therefore, Figure 1 is corrected to show such means identified by a reference number 30. And as discussed further in Section IV, the specification has been amended accordingly in the paragraph that begins on page 6, line 16, and the paragraph that begins on page 6, line 26. Because the means 30 for imposing a constraint to the center of rotation without immobilizing it was described in the originally-filed specification, no new matter is added by this amendment.

(3) The "calculation means" is described in the originally-filed specification at page 7, lines 3-22 but was not illustrated in originally-filed Figure 1. Therefore, Figure 1 is corrected to show such means identified by a reference number 40. And as discussed further in Section IV, the specification has been amended accordingly in the paragraph that begins on page 7 line 3. Because the calculation means 40 was described in the originally-filed specification, no new matter is added by this amendment.

Accordingly, approval and entry of the corrected Figure 1 are respectfully requested. Corrected Figure 1 and a Marked-Up copy of Figure 1 are attached herewith.

IV. AMENDMENT TO SPECIFICATION

The specification is amended to correct the informalities cited by the Examiner in his Objections to Drawings. The paragraph that begins on page 7, line 3 is amended to identify the "means 20 for locating several positions of the femur during motions thereof," recited in claim

12, and which was already illustrated in the originally-filed Figure 1. The paragraph now recites, in part, “Knowing several positions of point O and the corresponding femur orientations, as determined by means 20 for locating several positions of the femur during motions thereof, the problem to be solved to determine the position of point C is an optimization problem.” Because the means 20 for locating several positions of the femur during motions thereof was already illustrated in the originally-filed Figure 1, no new matter is added by this amendment.

The paragraph that begins on page 7, line 3 is further amended to identify the calculation means described therein and claimed in claim 12 with reference number 40. This paragraph now recites, in part, “Various calculation methods 40 for solving this problem may be used:” Because the calculation means 40 was described in the originally-filed specification, no new matter is added by this amendment.

The paragraphs that begin on page 6, line 16 and line 26 are amended to identify with a reference number 30, the “means for imposing a constraint to the center of rotation without immobilizing it,” recited in claim 12, and already described in these paragraphs in the originally-filed specification. No new matter is added by this amendment.

V. OBJECTIONS TO CLAIMS

The Examiner objected to claim 6 because it recites, in line 1, “a the”.

In response, claim 6 is corrected in relevant part to recite “the”. Applicant requests withdrawal of the objection and reconsideration of claim 6 in view of applicant’s response to claim rejections discussed herein.

VI. REJECTION UNDER 35 USC 112

The Examiner has rejected claims 1-12 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. This rejection is traversed.

Regarding claims 1, the Examiner states that the claim is not concise and exact as to (1) in what fashion and by what means the bone is displaced; (2) how the step of “locating several ones of its positions and memorizing them” is performed; (3) how the displacement of the center of rotation is constrained “without immobilizing it”; (4) how the step of “searching a point linked to the referential of said bone” is performed; and (5) what the “optimization criteria” comprises as this terminology does not have well established meaning.

With regard to item (1), applicant submits that in view of the originally-filed specification for example, at page 6, line 26 to page 7, line 22, including the references cited therein, it would be obvious for one of ordinary skill in the art to understand in what fashion and by what means the bone is displaced.

With regard to item (2), the originally-filed specification for example, at page 5, lines 21-32, including the article referenced therein, describes the step of locating several positions of the bone. As exemplified by the referenced article, the step of locating several positions of the bone are well known in the art.

With regard to item (3), the originally-filed specification for example, at page 6, line 26 to page 7, line 2, describes that the constraint is imposed to the center of rotation of a bone, the first femur, without immobilizing it by immobilizing a second bone, the patient’s opposite femur.

With regard to item (4), the originally-filed specification for example, at page 7, lines 3-22, including the articles cited therein, describes the step of searching a point linked to the referential of the bone. As exemplified by the referenced articles, the step of locating several positions of the bone are well known in the art.

With regard to item (5), applicant submits that in view of the disclosure in the originally-filed specification at, for example, page 7, lines 3-22, page 8 line 11 to page 9, line 16, incorporating the references cited therein, the concept of an “optimization criterion” in this context is well described and one of ordinary skill in the art would readily understand the term.

Accordingly, applicant believes that claim 1 is sufficiently enabled and meets the requirement of 35 U.S.C. §112, first paragraph.

Regarding claim 2, the Examiner states that the claim is not concise and exact as to how the step of “searching the invariants of this displacement, taking into account the fact that the center of rotations of the first and second femurs are distant by a substantially constant length” is performed.

The originally-filed specification, for example, at page 6, line 30 to page 7, line 2, describes such step.

Regarding claims 3-11, the Examiner broadly states without any specificity that “similar problems exist. Applicant, thus, assumes that the discussions provided above with respect to the Examiner’s rejection of claims 1 and 2 are also applicable to claims 3-11.

Regarding claim 12, the Examiner states that the claims is not enabling because the specification does not provide a full, clear and concise description of “how the method is used.” The Examiner further states that the only structural elements disclosed comprise mechanical systems for blocking the thigh and external markers. These structural elements do not constitute an adequate description to enable a person of ordinary skill in the art to make the device as claimed.

Since claim 12 recites a device, applicant assumes that the Examiner's reference to "the method" is a typographical error. Applicant disagrees with the Examiner that the disclosure is insufficient as to the structural elements of the means recited in claim 12. As discussed in reference to the rejection of claim 1, above, the means recited in claim 12 and the corresponding steps performed by those means (recited in claim 1) are sufficiently disclosed in the originally-filed specification. The step and means of locating several position of the femur during motions thereof are disclosed in the originally-filed specification at, for example, page 5, lines 21-32, including the references cited therein. The means and step for imposing a constraint to the motion of the center of rotation without immobilizing it are disclosed in the originally-filed specification at, for example, page 6, line 26 to page 7, line 2. The calculation means is disclosed in the originally-filed specification at, for example, page 7, lines 3-10 and further clarified by the amendment to that portion of the specification as provided herein. As discussed above in Section IV, the calculation means is now identified by reference number 40 in the amended specification.

Accordingly, in view of the discussions provided above, applicant believes that the Examiner's rejection of claims 1-12 under 35 U.S.C. § 112, first paragraph, has been overcome. Withdrawal of the rejection and reconsideration of claims 1-12 are respectfully requested.

Additionally, the Examiner rejected claims 1-12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-12, the Examiner states that the use of the pronouns "it", "its" and "them" render the claims indefinite.

In response, applicant amended claims 1, 2, 7 and 12 to replace the recitations of the pronouns with appropriate definite nouns.

Regarding claim 1, the Examiner notes that the limitation “the referential” does not have antecedent basis in the claim.

In response, applicant amended claim 1 to now recite “a referential”.

Further regarding claim 1, the Examiner states that the term “optimization criterion” lacks a well established and recognized meaning. This rejection is traversed.

Applicant submits that in view of the disclosure in the originally-filed specification at, for example, page 7, lines 3-22, page 8 line 11 to page 9, line 16, incorporating the references cited therein, the concept of “optimization criterion” in this context is well described and one of ordinary skill in the art would readily understand the term.

Regarding claims 2, 4, 6, 7 and 9, the Examiner notes that the limitation “the method for determining the center of rotation of a femur with respect to the iliac bone of claim 1” recited in these claims lack sufficient antecedent basis because there is no such method recited in claim 1.

In response, claim 1 is amended to now recite: “A method for determining the center of rotation of a first femur in a revolute joint of an iliac bone, comprising the steps of: . . .”

Regarding claim 2, the Examiner notes that the limitation “the invariants” lack sufficient antecedent basis.

In response, claim 2 is amended to now recite “invariants” without the preceding “the”.

Regarding claim 3, the Examiner notes that the limitation “each measurement” lack sufficient antecedent basis.

In response, claim 3 is amended to now recite: “The method of claim 2, further comprising the step of locating, *for each of the several positions of the first femur*, the position of the second femur to accordingly correct the position of the center of rotation between the first femur and the iliac bone.”

Further regarding claim 4, the Examiner notes that it is unclear what point the limitation “searching this point” is intended to refer to.

In response, claim 4 is amended to replace the limitation “searching this point” with “searching the center of rotation”.

Further regarding claim 4, the Examiner notes that the term “optimization method” lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite. This rejection is traversed.

Applicant submits that in view of the disclosure in the originally-filed specification at, for example, page 7, lines 3-22, page 8 line 11 to page 9, line 16, incorporating the references cited therein, the concept of “optimization method” in this context is well described and one of ordinary skill in the art would readily understand the term.

Further regarding claim 4, the Examiner notes that the limitation “a trajectory which is clearly mathematically distinct” lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite. This rejection is traversed.

Applicant submits that the disclosure in the originally-filed specification at page 8, line 11 to page 9, line 16 sufficiently describes what is meant by the cited limitation.

Regarding claim 6, the Examiner rejects the claim on the following bases: (1) that the phrase "can be" is indefinite; (2) the limitation "decomposed in several elementary motions" is indefinite; (3) the limitation "elementary motions" lacks a well established and recognized meaning; (4) the limitation "each of the estimations" lacks sufficient antecedent basis; and (5) the terms "optimal" and "optimized" lack a well established and recognized meaning and thus indefinite.

In response, claim 6 is amended to now recite: "The method for determining the center of rotation of a femur with respect to the iliac bone of claim 4, further comprising:

decomposing the thigh motion in several elementary motions,
for each elementary motion, an optimal center of rotation and an optimized distance value
are calculated,

statistically defining the center of rotation, taking into account each of the calculated
center of rotation and the optimized distance value, obtained based on each of the elementary
motions." The amended claim 6 corrects Examiner's bases for rejection (1) and (4) identified by
the Examiner.

Regard to Examiner's bases (2), (3) and (5), applicant respectfully traverses these
rejections.

Applicant submits that in view of the disclosure of the originally-filed specification, for example, at page 7, lines 3-22, page 8, line 11 to page 9, line 16, including the references cited therein, describing the motions of the thigh and the femur bones involved and the optimization

method of calculating the center of rotation of the first femur bone, these limitations are not indefinite and would be readily understood by one of ordinary skill in the art.

Regarding claim 7, the Examiner states that the limitation “as simple a trajectory as possible” is a broad limitation and the subsequent recitation of “in particular, no loops” is a narrower statement of the range/limitation, rendering the claim indefinite.

In response, claim 7 is amended to delete the recitation of “in particular, no loops”.

Further regarding claim 7, the Examiner states that the limitation “searching this point” is indefinite.

In response to the Examiner’s concern (1), claim 7 is amended in relevant part to now recite: “searching the center of rotation” instead of “searching this point”.

Further regarding claim 7, the Examiner states that the term “optimization method” lacks a well established and recognized meaning. This rejection is traversed.

As discussed in reference to the same limitation recited in claim 4, applicant submits that this limitation is not indefinite in view of the disclosure in the originally-filed specification and that one of ordinary skill in the art would readily understand the meaning of the term in view of the disclosure.

Further regarding claim 7, the Examiner states that the term “as simple as possible” lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that the disclosure in the originally-filed specification at, for example, page 9, last paragraph, sufficiently defines what is meant by the term “as simple as possible” in the context of the invention as claimed in claim 7.

Further regarding claim 7, the Examiner states that the term “mathematically simple” lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that the disclosure in the originally-filed specification at, for example, page 8, line 11 to page 9, line 16, and page 9, line 29 to page 10, line 10, sufficiently defines what is meant by the term “mathematically simple” in the context of the invention claimed in claim 7.

Regarding claim 8, the Examiner rejects the claim on the following bases: (1) that the phrase “can be” is indefinite; (2) the limitation “decomposed in several elementary motions” is indefinite; (3) the limitation “elementary motions” lacks well established and recognized meaning and thus indefinite; (4) the limitation “the optimized distance” lacks sufficient antecedent basis; and (5) the limitation “each of the estimations” lacks sufficient antecedent basis.

In response to the Examiner’s bases (1), (4) and (5), claim 8 is amended to now recite: “The method of claim 7, further comprising:

decomposing the thigh motion in several elementary motions,
for each elementary motion, an optimal center of rotation and the value of an optimized distance are calculated,

the center of rotation is statistically defined, by taking into account each of the calculated center of rotation and the value of the optimized distance, obtained based on each of the elementary motions.”

With regard to the Examiner's bases (2) and (3), applicant respectfully traverses these rejections.

As discussed above in reference to the same limitations recited in claim 6, applicant submits that in view of the disclosure of the originally-filed specification, for example, at page 7, lines 3-22, page 8, line 11 to page 9, line 16, and page 10, lines 11-22, including the references cited therein, describing the motions of the thigh and the femur bones involved and the optimization method of calculating the center of rotation of the first femur bone, these limitations are not indefinite and would be readily understood by one of ordinary skill in the art.

Regarding claim 9, the Examiner states that the limitation "a succession of elementary motions" is indefinite. Further, the limitation "elementary motions" lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that in view of the disclosure of the originally-filed specification, for example, at page 7, lines 3-22, page 8, line 11 to page 9, line 16, and page 10, line 23 to page 11, line 17, including the references cited therein, describing the motions of the thigh and the femur bones involved and the optimization method of calculating the center of rotation of the first femur bone, these limitations are not indefinite and would be readily understood by one of ordinary skill in the art.

Further regarding claim 9, the Examiner states that the limitation "high" lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that the limitation “high” in this context is sufficiently defined in the originally-filed specification at page 10, lines 23-35. Specifically, the specification defines a probability of greater than 95% as being “high.” Thus, the meaning of this term is not indefinite.

Regarding claim 10, the Examiner states that the term “elementary motions” lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that for the same reasons discussed in reference to the same limitation recited in claims 8 and 9, this limitation is not indefinite.

Further regarding claim 10, the Examiner states that the term “small” lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

The term “small” is used in the limitation “some of the elementary motions of the thigh are performed in a plane and are of small amplitude.” This limitation is defined in the originally-filed specification at, for example, page 4, line 23-25, and page 10, line 35 to page 11 line 10. The description on page 11 states that according to the present invention, “motions of the thigh with a low urge of the ligamentary, capsular, and muscular apparatus ensuring the cohesion between the femur and the pelvis may be chosen.” And further states that “such motions are for example rotating motions of the femur around its axis, or motions where the femur end moves with a sufficiently limited amplitude, describing for example approximately in a plane a portion of a circle, said plane being likely to contain, for example, approximately the center of rotation or to be approximately perpendicular to the axis formed by the center of rotation and the center of said circle.” No new matter is added.

Regarding claim 11, the Examiner states that the term “elementary motions” lacks a well established and recognized meaning and thus indefinite. This rejection is traversed.

Applicant submits that for the same reasons discussed in reference to the same limitation recited in claims 8, 9 and 10, this limitation is not indefinite.

Regarding claim 12, the Examiner states that the limitation “the referential” lacks sufficient antecedent basis.

In response, claim 12 is amended to recite “a referential” instead of “the referential”.

Further regarding claim 12, the Examiner states that the term “minimization criterion” lacks a well established and recognized meaning and thus indefinite.

In response, claim 12 is amended to correct this typographical error and now recites: “optimization criterion” instead of “minimization criterion”. This amendment is fully supported by the specification as originally-filed and the term “optimization criterion” is not indefinite for the same reasons discussed above in reference to claims 1, 4 and 7 reciting the same term.

Further regarding claims 1, 2, 4 and 12, the Examiner states that the claim language is contradictory of itself and as such renders the claim indefinite.

Applicant submits that based on the particular sections of the disclosure in the originally-filed specification discussed in reference to claims 1 and 12, above, and the references cited in those sections of the specification, the claims language is not contradictory. In particular, there is no contradiction in not immobilizing the bone and restraining its rotation. As explained in the originally-filed specification at page 6, last paragraph, the rotation of one femur is restrained by immobilizing the patient’s other femur.

Accordingly, applicant believes that the Examiner's rejection of claims 1-12 under 35 U.S.C. § 112, second paragraph, has been overcome. Withdrawal of this rejection and reconsideration of claims 1-12 are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. §102

Independent claims 1 and 12 are rejected as being anticipated by U.S. Patent No. 5,601,566 to Dance *et al.* ("Dance"). This rejection is traversed.

Dance discloses a method for the element of femoral knee prosthesis without the need of X-rays, estimation, calculation, location of hidden or obscured landmarks (Dance at column 2, lines 45-47). In contrast, the present invention claimed in claims 1 and 12 uses calculation means and not only mechanical means to find the center of rotation of a bone, such as a femur, in a revolute joint. Accordingly, Dance does not teach or suggest the novel features of the present invention.

Applicant respectfully requests withdrawal of the rejection, reconsideration and allowance of the amended claims 1 and 12.

With regard to amended claims 2-11, these claims ultimately depend from and include all the subject matter contained in independent claim 1. Accordingly, claims 2-11 are also believed to be allowable by virtue of their dependence on allowable base claim.

VII. OTHER AMENDMENTS TO THE CLAIMS

In addition to the amendments discussed above, claims 1-12 are amended further to comply they form to U.S. format. In particular, the recitation of "characterized in that" in the

originally filed claims are replaced with "comprising", "further comprising" or "wherein" as appropriate.

If the Examiner believes the prosecution of this application would be advanced by a telephone call, the Examiner is invited to contact applicant's attorney at the telephone number indicated below.

VIII. FEES

A fee in the amount of \$475.00 for three months extension of time for filing this paper is believed due. Please charge the fee and any additional fee that may be due do Duane Morris
Deposit Account No. 50-2061.

Respectfully submitted,

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Enclosures: Corrected drawing sheet (1)
Marked-Up drawing sheet (1)